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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,824	04/21/2004	Kenneth Bolam	PM0344	7277

7590 10/30/2006
Amersham Health, Inc
IP Department
101 Carnegie Center
Princeton, NJ 08540

EXAMINER

MATTER, KRISTEN CLARETTE

ART UNIT	PAPER NUMBER
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3771

DATE MAILED: 10/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/828,824	BOLAM ET AL.	
	Examiner	Art Unit	
	Kristen C. Matter	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-63 is/are pending in the application.
- 4a) Of the above claim(s) 1-26 and 50-59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) 27-41 and 43-49 is/are allowed.
- 6) ☒ Claim(s) 42 and 60 is/are rejected.
- 7) ☒ Claim(s) 61-63 is/are objected to.
- 8) ☒ Claim(s) 1-63 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 4/21/04 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/10/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121.

This application contains the following inventions or groups of inventions, which are not independent and distinct:

Group I, claims 1-52 and 60-63, drawn to ventilator systems and method for delivering hyperpolarized gas to a patient.

Group II, claims 53-59, drawn to a computer program product for delivering hyperpolarized gas to a patient.

Inventions Group I and Group II are related as combination and subcombination.

Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the systems and method of Group I can deliver hyperpolarized gas to a patient using manual adjustments to a controller or with a different program inputted into the controller. The subcombination has separate utility such as delivering oxygen to pilots in an aircraft and to deliver gas in a CPAP device.

The examiner has required restriction between combination and subcombination inventions. Where applicant elects a subcombination, and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Furthermore, if applicant elects Group II above, they must further choose between the following patentably distinct species:

Group I(a), claims 1-26 and 50-52, drawn to ventilator systems for delivery of hyperpolarized gas without controllable fluidic capacitance volume explicitly needed.

Group I(b), claims 27-49 and 60-63, ventilator system and method for delivering hyperpolarized gas to a patient using controllable fluidic capacitance volume.

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The species are independent or distinct because Group I does not necessarily adjust fluidic capacitance volume to stabilize the pressure upstream of the gas delivery valve. Group II comprises controllably increasing and decreasing fluidic capacitance volume in response to pressure measurements.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

During a telephone conversation with Robert Chisholm on September 27, 2006, a provisional election was made without traverse to prosecute the invention of Group I(b), claims 27-49 and 60-63. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-26 and 50-59 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 42 and 60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 42 recites “Gas A” and “Gas B” throughout the claim. “Gas A” and “Gas B” lack antecedent basis and therefore render the claim vague and indefinite. Examiner suggests the following changes: lines 2, 3, 5, and 6, “Gas A” should be changed to --gas--; lines 3 and 4, “Gas B” should be changed to --gas--; lines 5 and 6, “Gas B” should be changed to --non-polarized gas--.

Claim 60 recites “at least about 10 times greater than the volume of the lungs of the subject”. It is unclear what the metes and bounds of the claim is because it is unclear what respiratory volume the applicant is referring to. Examiner suggests changing “at least about 10 times greater than the volume of the lungs of the subject” to --at least about 10 times greater than the tidal volume of the lungs of the subject--.

Allowable Subject Matter

Claims 27-41 and 43-49 are allowed over the prior art of record.

Claims 61-63 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is an examiner’s statement of reasons for allowance:

- The prior art of record does not disclose or render obvious the combination of structural limitations found in independent claim 27. Specifically, the prior art of record does not teach a method of delivering hyperpolarized gas to a subject comprising, providing a ventilator system with a mass flow controller, a tracheal tube, and a gas delivery valve configured to deliver hyperpolarized gas and at least one non-polarized gas to a subject by monitoring two one pressure upstream and one pressure downstream of the gas delivery valve, obtaining a reading of the mass flow controller when the pressure upstream is constant and then automatically determining the tidal inspiration volume of hyperpolarized gas delivered to the subject using the mass flow controller reading.
- The prior art of record does not disclose or render obvious the combination of structural limitations found in dependent claims 61-63 with those in independent claim 60 as best understood by the examiner. Specifically, the prior art of record does not teach a ventilator system comprising a gas delivery valve configured to selectively dispense a plurality of gases, a mass flow controller, a polarized gas source, a second gas source, a pressure sensor located upstream of the gas delivery valve, a second pressure sensor located downstream of the gas delivery valve, and a manifold line having a fluidic tunable capacitance disposed upstream of the gas delivery valve.

The notation “of record” refers specifically to art that is cited in this case.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen C. Matter whose telephone number is (571) 272-5270. The examiner can normally be reached on Monday - Friday 9-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Kristen C. Matter
Examiner
Art Unit 3771



JUSTINE R. YU
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

10/23/06